ANDA 75-413 December 21, 1999

Geneva Pharmaceuticals, Inc.
Attention: Beth Brannan, Director
Drug Regulatory Affairs
2555 W. Midway Boulevard
Broomfield, CO 80038-0446

Dear Madam:

This is in reference to your abbreviated new drug application dated July 9, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Buspirone Hydrochloride Tablets USP, 5 mg, 10 mg, and 15 mg.

Reference is also made to your amendments dated August 11, September 18, October 2 and November 3, 1998; and January 4, February 17, March 15, May 24, July 23, November 4 (2 submissions), November 24, and December 3, 1999.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug product is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved**. This determination is based upon information available to the Agency at this time, (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product (RLD) referenced in your application, Buspar Tablets of Bristol Myers Squibb Co. Pharmaceutical Research Institute, is subject to periods of patent protection which expire on May 22, 2000, (U.S. patent 4,182,763, the '763 patent) and May 14, 2008, (U.S. patent 5,015,646, the '646 patent). Your application contains a Paragraph IV Certification to the '646 patent under Section

505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on this patent. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified the Agency that Geneva Pharmaceuticals, Inc. (Geneva) has complied with the requirements of Section 505(j)(2)(B) of the Act and that no action for infringement against the '646 patent was brought against Geneva within the statutory forty-five day period. In addition, your application contains a Paragraph III Certification to the '763 patent under Section 505(j)(2)(A)(vii)(III) of the Act. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until the ‘763 patent has expired, i.e., currently May 22, 2000.

Because the agency is granting a tentative approval for this application, please submit an amendment at least 45 days prior to the date you believe your application will be eligible for final approval; i.e., the expiration of the '763 patent. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved and should include updated information such as final printed labeling to reflect appropriate changes made to the labeling of the reference listed drug (RLD), as well as updated chemistry, manufacturing, and controls data as appropriate. Alternatively, an amendment should be submitted even if none of these changes were made. This submission should be clearly designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an additional amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant change in the conditions outlined in this abbreviated application, as well as changes in the status of the manufacturing and testing facilities’ compliance with current good manufacturing practices (CGMPs) are subject to agency review before final approval of the application will be

made.

Prior to the issuance of a final approval letter by the Agency, your product will not be deemed approved for marketing under 21 U.S.C. 355 and not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the “Orange Book”), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to the expiration of the ‘763 patent on May 22, 2000, you should amend your application accordingly.

Prior to submitting an amendment, please contact Mr. Joseph Buccine, Project Manager, at (301) 827-5754, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 311(d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research